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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/602,272	02/16/1996	MICHAEL J. ELLIOTT	KIR96-01	4297

7590 03/10/2006  
JOHN P. WHITE, ESQ. COOPER & DUNHAM  
1185 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1643

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/602,272

Applicant(s)

ELLIOTT ET AL

Examiner

Karen A. Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 6,9,10,12-15,29,31,32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 6, 9, 10, 12-15, 29, 31, 32 and 34-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some.\* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

1. Claims 8, 30 has been canceled. Claims 6, 9, 10, 12, 29, 31, 32 and 34 have been amended, Claims 6, 9, 10, 12-15, 29, 31, 32 and 34-37 are pending and under consideration.
2. Sections of Title 35, U.S. Code not found in this action, can be found in a prior action.
3. The rejection of claims under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement is maintained for reasons of record.

The rejection of claims 6, 9, 10, 12-15, 29, 31, 32 and 34-37 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the following reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims have been amended to incorporate the limitation of "a subject diagnosed as suffering from thrombosis". The specification and claims as filed are drawn to the treatment of thromboembolic disorders, where the thromboembolic disorder includes deep vein thrombosis (original claims 7 and 8). Neither the specification nor the originally filed claims provide support for limiting treatment to subjects "diagnosed" as suffering from thrombosis. Further, neither the specification nor originally filed claims provide support for the broadly claimed treatment of "thrombosis" rather than the treatment of deep-vein thrombosis as recited in the specification and originally filed claims, nor the broadly claimed method of decreasing the level of plasma fibrinogen in a subject as diagnosed with thrombosis. Amendment to broaden the disclosed method of treating "deep venous thrombosis" to a method of treating thrombosis is not supported by the originally filed disclosures in light of the fact that art recognizes numerous molecular defects which cause a subject to be in a prethrombotic state such as inherited as acquired disorders of antithrombin III deficiency, Protein C and S deficiency, Dysplasminogenimia, Dysfibrinogenemia, defective release and diminished venous content of PAI, excessive release of PAI, Homocystineurea, chronic congestive heart failure, Metastatic tumors, extensive trauma or major surgery, Myeloproliferative disorders, Behcet's syndrome, Kawasaki's disease, treatment with oral contraceptives and treatment with GM-CSF (Handin, R.

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'Disorders of Coagulation and Thrombosis', In: Harrison's Principles of Internal Medicine, 13th Ed., Vol. 1, Isselbacher et al, Ed., pp. 1804-1810, see Table 315-3) and one of skill in the art would not conclude upon reading of the specification, that the instant method would include the broadly claimed treatment of thrombosis rather than the treatment of deep-venous thrombosis.

4. Applicant argues that the specification defines thrombotic disorders as those disorders wherein thrombosis is the pathogenic component. Applicant argues that one of skill in the art would have recognized that plasma fibrinogen levels can be controlled and thrombosis in an individual can be treated by the same method. This has been considered and found persuasive. However, the specification still lacks support for the treatment of subjects "diagnosed" versus those subjects who were treated with the disclosed anti-TNF antibody but not diagnosed as suffering from thrombosis.

5. All other rejections and objections are withdrawn in light of applicants amendments and arguments.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

3/6/2006

  
KARENA. CANELLA PH.D.  
PRIMARY EXAMINER